5.0 510(k) Summary

SEP 2 8 2011

1. Sponsor

SpineFrontier, Inc.
500 Cummings Center
Suite 3500
Beverly, MA 01915

Primary Contact: Hannah Foley
Telephone: 1- 978-232-3990

Date Prepared: May 9, 2011

2. Device Name and Classification:

Proprietary Name:	SpineFrontier Lumbar IBF System
Common/Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification Name:	Intervertebral Fusion Device With Bone Graft, Lumbar, (21 CFR 888.3080), Class II
Product Code:	MAX

3. Predicate Devices

This 510(k) submission provides notice of design changes being implemented to SpineFrontier's Dorado, Dorado Wide, and SLIF intervertebral body fusion devices and to create the SpineFrontier Lumbar IBF System. These modifications do not alter the fundamental technology of the predicate device or the devices' intended use.

K072289 – SpineFrontier Inc., Dorado Intervertebral Body Cage
K091638 – SpineFrontier Inc., Dorado Wide IBF
K092815 – SpineFrontier Inc., S-LIF IBF
K071724 – Spinal Elements, Lucent

4. Device Description

The **SpineFrontier Lumbar IBF System** is a spinal intervertebral body fusion device system intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The system is comprised of devices made of PEEK Optima® LT1, with varying widths, lengths, and heights to fit the anatomical needs of patients. The devices have raised contours on the superior and inferior surfaces that will resist device movement following implant.

5. Intended Use

The **SpineFrontier Lumbar Interbody Fusion Device System** (Dorado IBC, Dorado PLIF, Dorado ELIF, Dorado ALIF, Dorado TILT, Dorado TLIF, Dorado Wide, and Ursa S-LIF) is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The **SpineFrontier Lumbar Intervertebral Body Fusion Device System** is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine.

6. **Technological Characteristics**
   The **SpineFrontier Lumbar Intervertebral Body Fusion Device System** was shown to be substantially equivalent to predicate devices through comparison of indications for use, function, operating principles, and materials.

7. **Basis for Substantial Equivalence**
   The **SpineFrontier Lumbar Intervertebral Body Fusion Device System** was evaluated in accordance with FDA Document, *Class II Special Controls, Guidance Document: Intervertebral Fusion Device, June 12, 2007*, and has been found to meet criteria defined in the guidance document; and has been demonstrated to be substantially equivalent to predicate devices in terms of indications for use, function, materials, and performance (mechanical testing). Clinical data was not required for this device. Mechanical testing includes performance assessments per the following recognized test methods:
   - ASTM F2077-03, Static and Dynamic Axial Compression, Static Torsion, and Static and Dynamic Shear Compression
   - ASTM F2267-04, Subsidence Under Static Axial Compression
   - ASTM Draft Standard F-04.25.02.02, Static Expulsion

SpineFrontier, Inc.
% Ms. Hannah Foley
Manager of QA and Regulatory Compliance
500 Cummings Center, Suite 3500
Beverly, Massachusetts 01915

SEP 28 2011

Re: K111553
Trade/Device Name: Lumbar IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 07, 2011
Received: September 09, 2011

Dear Ms. Foley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin K Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K111553

Device Name: SpineFrontier Lumber Interbody Fusion Device System

Indications For Use:

The **SpineFrontier Lumbar Interbody Fusion Device System** (Dorado IBC, Dorado PLIFT, Dorado ELIFT, Dorado ALIFT, Dorado TILT, Dorado TLIFT, Dorado Wide, and Ursa S-LIFT) is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The **SpineFrontier Lumbar Intervertebral Body Fusion Device System** is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine.

Prescription Use: X OR **Over-The-Counter Use:** _____
(Part 21 CFR 807.109)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111553